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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,314	03/09/2006	Jean-Pascal Zambaux	06023	8360
23338	7590	05/10/2011		
DENNISON, SCHULTZ & MACDONALD 1727 KING STREET SUITE 105 ALEXANDRIA, VA 22314			EXAMINER	
			GRAY, PHILLIP A	
			ART UNIT	PAPER NUMBER
			3767	
			MAIL DATE	DELIVERY MODE
			05/10/2011 PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/571,314

Applicant(s)

ZAMBAUX ET AL.

Examiner

Phillip Gray

Art Unit

3767

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-912)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to applicant's communication of 2/25/2011. Currently claims 1-15 are cancelled and newly added claims 16-30 are pending and rejected below.

Response to Arguments

Applicant's arguments with respect to claims 1-15 have been considered but are moot in view of the new ground(s) of rejection. Applicant's have cancelled claims 1-15 and added new claims 16-30.

Applicant argue that Palasis reference teaches that PEEK is incompatible with pharmaceutical materials, and when the wall surrounding the lumen comprises PEEK, a barrier layer between the PEEK and the lumen is required. And further the barrier layer is excluded by the invention as claimed.

Examiner disagrees with the applicants position. It is examiners position that a secondary (another) embodiment of Palasis discloses using a barrier layer. And that Palasis may be made of an embodiment which has a PEEK wall in contact with a central lumen, (i.e. a simply one piece needle made of PEEK or a PEEK needle reinforced with a metal reinforcement.) See Palasis paragraph [86] below.

[0086] Moreover, the polymer should meet any structural requirements. Numerous methods are available to provide structural integrity or flexibility to polymers. For example, in the event that the pharmaceutical article comprises a needle (or cannula) for delivery or aspiration, a polymeric needle can be fashioned from several of the materials listed above, notably, polyimide, PTFE, PET, polyphenylene

sulfide (PPS), polysulfone (PS) and PEEK, which have excellent rigidity and the ability to be sharpened into a needle. Additional materials are disclosed in U.S. Pat. No. 4,838,877, including, polycarbonates, polyetherimides, polymethylpentenes, polyesters, acrylates, polyaramides, polyamides, modified phenylene oxides, and polysulfones. Alternatively, where enhanced strength and/or rigidity are desired, the polymeric material can be reinforced, for example, by fibers. For example, U.S. Pat. No. 5,637,399 discloses a synthetic resin needle of reinforced with combustible fibers whose longitudinal directions are arrayed straight or curvilinearly along the axial length of the needle. Numerous resins are listed, from which one of ordinary skill in that art can select and test for compatibility, for example, using the procedures set forth in the Examples. Metal or ceramic reinforcements may be included in addition to combustible fibers.

Therefore it is examiners position that Palasis discloses a simple PEEK wall needle with metal reinforcement. Therefore applicant's arguments concerning Palasis are not persuasive. However Examiner is provided a new prior art rejection in light of the newly added claims, under Yoshikawa et al. and Preissman. See rejection below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshikawa et al. (U.S. Patent 5,637,399) in view of Preissman (U.S. Patent 6,348,055)

Yoshikawa discloses constructing a needle comprising a cylindrical hollow body with a central lumen surrounded by a wall (see abstract and paragraphs at Column 2 lines 11-50), the body being beveled at one end (column 3 lines 25-39), the wall in contact with the central lumen comprising a polyaryletherketon polyer (PEEK or Polyether etherketoneas in paragraphs at columns 2 lines 12-27), the needle further comprising at least three reinforcement wires embedded in the polymer and extending parallel to the longitudinal axis and being even-tensioned throughout the length of hollow body (see column 1 lines 47 through column 2 lines 4) and distributed such that any pair of wires defines an identical center angle see column 3 lines 40-50 for

example). Concerning claim 21 and the hollow body being circular see note hollow tube shape column 1 line 60). Concerning claim 17 and the filler materials see Yoshikawa at column 3 lines 50-62.

Yoshikawa discloses the claimed invention except for the at least three reinforcement wires embedded made of steel. Preissman teaches that it is known to use at least three reinforcement wires embedded made of steel as set forth in [figures 8-9 and paragraphs at column 9 lines 25-65 to provide a means to reinforce, support the tube maintain structural integrity and advantages for radiographic viewing. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Yoshikawa with at least three reinforcement wires embedded made of steel as taught by Preissman, since such a modification would provide the system with at least three reinforcement wires embedded made of steel for providing a means to reinforce, support the tube maintain structural integrity and advantages for radiographic viewing.

Concerning claim 20, Yoshikawa et al. in view of Preissman discloses the claimed invention except for the wires being elliptical rather than circular. It would have been an obvious matter of design choice to craft the circular wires in an elliptical shape, since applicant has not disclosed that elliptical wires solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the circular wires. Further a change in shape of a prior art device is a design consideration within the skill of the art. A PHOSITA is well aware of the similarity and interchangeability of a circular and/or elliptical wire shape in the industry.

Claims 22-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshikawa et al. in view of Preissman as applied to claims 16-21 above, and further in view of Stawski. Stawski discloses a syringe (50) with injection needle beveled on both ends (60') a piston (66), a recipient connector (51) with a first hollow section and second hollow section (top and bottom of 53), a horizontal wall (52), and a means for perforation (62 needle), a port for admission of gas (70), means for attachment (59) see figures 3-4. Stawski discloses the claimed invention except for the PEEK needle with steel reinforcements. Yoshikawa et al. in view of Preissman teaches that it is known to use the PEEK needle with steel reinforcements as set forth in rejection above to provide a biocompatible, durable, and control pharmaceutical effectiveness. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Stawski with a PEEK needle with steel reinforcements as taught by Yoshikawa et al. in view of Preissman, since such a modification would provide the *system* with a PEEK needle with steel reinforcements for providing a biocompatible, durable, and control pharmaceutical effectiveness.

Concerning claims 24-25, and 29-30, Yoshikawa et al. in view of Preissman, in further view of Stawski discloses the claimed invention except for the piston, pump body, and connector (hollow sections and horizontal wall) being made of a PEEK polymer with carbon fiber fillers. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the piston, pump body, and connector of a PEEK polymer with carbon fiber fillers, since it has been held to be within

the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). Further Yoshikawa already discloses the material is useful for its rigidity and forming of tubular bodies in medical devices and fluid delivery devices.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "Piston" and "piston comprises a polyaryletherketon polymer" (as in claims 23-25) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The "Piston" and "piston comprises a ployaryletherketon polymer" (as in claims 23-25) must be described in such a way to ascertain its structure, function, operational and spatial orientation within the device and the related elements. There is not an adequate description in the specification, and no inclusion in the drawings of the element and structure of the claimed feature. Appropriate correction is required.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phillip Gray/
Examiner, Art Unit 3767

/Theodore J Stigell/
Primary Examiner, Art Unit 3763